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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,822	05/26/2000	Gyorgy Lajos Kis	OP/V-30969A	9338

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EXAMINER

CONLEY, SEAN E

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 06/04/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-9

Office Action Summary

Application No.

09/580,822

Applicant(s)

KIS ET AL.

Examiner

Sean E Conley

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed February 27, 2002 has been received and considered for examination. Claims 1-14 have been canceled and new claims 15-20 have been added.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 15- 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1,544,260 in view of EP 0322134.

GB 1,544,260 discloses a method for sterilizing a pharmaceutical package wherein the package is placed in a sterilizing autoclave chamber **38** and the pressure and temperature is adjusted as a function of time. The pressure and temperature adjustments depend on the size and materials of the container to be sterilized. These pressure and temperature adjustments are controlled electronically by a control system **54**. (see page 1, lines 64-96 and page 2, lines 1-13 & 97-112). The regulating of the pressure and temperature by the control system prevents deformation of package being sterilized. The reference also discloses that the internal volume of the package exceeds the volume occupied by the liquid contents meaning that there have not been any precautions taken to avoid the presence of air in the closed package. The specific package material disclosed in the reference is a nylon-polypropylene-polyethylene copolymer laminated sheet that is formed into a tube. The invention of GB 1,544,260 does not specifically teach sterilizing a polypropylene bottle or a polypropylene foil laminated tube.

EP 0322134 discloses a method of packaging and steam sterilizing a pharmaceutical product. The pharmaceutical product to be sterilized is a polypropylene bottle and once the bottles are prepared for sterilization they are inserted into an autoclave. The autoclave serves the purpose of sterilizing the bottles using an application of steam. (see column 3, line 29 –column 6, line 12 and figures 1 and 2). The reference of EP 0322134 further teaches that the lids or caps can be formed of other polymeric materials other than polypropylene (see column 3, lines 29-49). Another well-known material used to make pharmaceutical packages is polyethylene and furthermore, high-density polyethylene is known to have a high heat resistance and withstands heat sterilization. Therefore, the use of other materials such as high-density polyethylene would result in a modulus of elasticity that is different than polypropylene. This reference has been relied on specifically to teach that it is known to sterilize polypropylene bottles with a heat generating apparatus such as an autoclave and furthermore, the bottle can be manufactured from other polymeric materials other than polypropylene..

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the pharmaceutical package of GB 1544260 (nylon-polypropylene-polyethylene copolymer laminated sheet that is formed into a tube) with the heat sterilizable package taught by EP 0322134 (polypropylene bottle) if one wanted to use the method of GB 1544260 to sterilize a polypropylene bottle and prevent deformation of the container by regulating the pressure and temperature inside the autoclave.

Regarding the wall thickness of the package, it is a well-known standard to one of ordinary skill in the art that pharmaceutical packages made of polypropylene have a wall thickness in the range of 0.3 mm to 0.6 mm.

Response to Arguments

6. Applicant's arguments filed February 27, 2002 regarding the combination of the references GB 1,544,260 and EP 0322134 have been fully considered but they are not persuasive. The reference EP 0322134 has been relied upon to specifically teach that is known to sterilize polypropylene bottles with a heat generating apparatus such as an autoclave. Furthermore, if one was to use the method of GB 1,544,260 to sterilize a polypropylene bottle they would not completely fill the bottle based on the method taught by GB 1,544,260. The method of GB 1,544,260 teaches process of sterilizing a container by regulating the pressure and temperature of the atmosphere inside and outside of the package in order to prevent any distortion. Therefore, if one wanted to use that method taught by GB 1,544,260 to prevent distortion then the bottle would have an internal volume that exceeds the volume occupied by the liquid contents.

7. The applicant's amendment necessitated the new grounds of rejection. Therefore, this office action has been made final.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Conley, whose telephone number is (703) 305-2430. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920. The Unofficial fax phone number for this group is (703) 305-7719. The Official fax phone number for this Group is (703) 872-9310.

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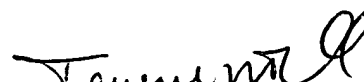
draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite the processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [robert.warden@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, whose telephone number is (703) 308-0661.

May, 8, 2002

SEC


Terrence R. Tili
Primary Examiner